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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,047	08/19/2003	Ronald B. Luther	RLUTHER.005C1	5133
20995	7590	04/23/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			ROBINSON, DANIEL LEON	
			ART UNIT	PAPER NUMBER
			3742	

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/644,047	Applicant(s) LUTHER ET AL.	
	Examiner Daniel I. Robinson	Art Unit 3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-1-2003</u> | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,587,893 (Luther et al.) in view of Howell (U.S.Pat.5,830,190). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed hardness of the catheter material (ie. 50-90 on the Shore A durometer scale) is included in range specified in the patent as 60-90 on the Shore A durometer scale. The hardness of catheter distal end of the claimed invention is "above about 90"(claim 2)on the Shore A durometer scale is claimed in the patent as "at least 75 on the Shore hardness D", and although Shore A and Shore D scales are not generally comparable a correlation exists for materials of similar resiliencies, and for plastics and elastomers at least 75 on the Shore D" is comparable to" above about 90" Shore A. The fact that the two materials in question are of similar resiliency is evidenced by claims 1 and 2 of the claimed invention where the hardness of the distal end is in the range of the hardness claimed for the rest of the catheter. The metal ring of claim 10 is claimed , in claim 9 of the patent as a "sleeve is fabricated from metal" and in claim 10 of the patent as "a radiopaque material". The "insertion needle", claim 8, of the claimed invention is shown as part 12 and called an introducer in claim 1 of the patent. The insert of claim 5 of the claimed invention is claimed in the patent as a " rigid tubular sleeve", claim 1 part 54, figs. 4 and 5, of the patent. U.S.Pat. 5,957,893 does not show a guard that covers the needle tip. Howell U.S.Pat. 5,830,190 discloses a protected needle catheter that shows a tip guard. It would have been obvious to one of ordinary skill in the art of over the needle catheters to provide a guard tip as taught by Howell for the device of U.S.Pat. 5,957,893 because the guard prevents inadvertent access to the needle tip.

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The method claims 12-19 are not explicitly claimed but obvious to one of ordinary skill in the art of catheter introduction (ie. a nurse presented with U.S. Pat. 5,957,893) because all apparatus limitations claimed as provided in the application are included in U.S. Pat. 5,957,893 and it would be obvious to one of ordinary skill in the art of over the needle catheters to introduce a needle into a catheter then insert the catheter into a patient's vascular system and then withdraw the needle from the catheter to permit connection of a proximal end of the catheter to a tube for fluid communication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel I. Robinson whose telephone number is 703 306-9043.

The examiner can normally be reached on M-F 5:30am-2:30pm.

The fax phone numbers for the organization where this application or proceeding is assigned are 305-3463 for regular communications and 305-3463 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0861.

DANIEL ROBINSON
PATENT EXAMINER
